Independent Scientific Advisory Committee for MHRA database research (ISAC)

Minutes of the meeting held on Tuesday October 22, 2013 at 11:00am in [R-T-410], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.

Present
ISAC Members:      MHRA:
Prof Patrick Waller (Chair)       Dr John Parkinson (CPRD) Items 4-5
Dr Krishnan Bhaskaran       Ms Kendal Chidwick (CPRD Secretary) All items
Dr Benjamin Cairns       Ms Helen Strongman (CPRD) Item 6
Prof Jacqueline Cassell       Ms Jessie Oyinlola (CPRD Secretariat) Items 1-6
Dr Christopher Edwards       Mr Tim Williams (CPRD) Items 9-10
Prof Peter Helms       Ms Tarita Murray-Thomas (CPRD) Item 11
Dr Iskandar Idris
Dr Umesh Kadam
Prof Benjamin Lipsky
Prof Simon Mitchell
Ms Marcia Saunders
Dr Richard Stevens
Dr Ruben Thanacoody

1. Introductions, apologies and announcements
   1.1. The Chair reminded members that the meeting materials are confidential and should not be disclosed. Members were also reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in the agenda items.
   1.2. Apologies were received from Richard Martin, Ms Sally Malin and Prof Martin Gulliford.

2. Minutes of the ISAC meeting held on Wednesday 10th July, 2013 and summary minutes for publication on the MHRA website
   2.1. Full and summary minutes were reviewed and approved without comment.
   2.2. A copy of the minutes was endorsed by the Chair.
   2.3. Summary minutes will be published on the MHRA website. Action MHRA.

3. Matters arising from the minutes
   3.1. The DH has accepted the ISAC member appraisal process and it has since been used to during the reappointment process of three members (see agenda item 15)

   CPRD Data

4. Verbal Update from Dr. Parkinson on CPRD matters
   4.1. John Parkinson provided an overview on the CPRD since the July 2013 meeting

5. Future arrangements for the Chairmanship of ISAC
5.1. The Chair and the Director of CPRD presented this item.
5.2. Members agreed with the proposal to recruit a Deputy Chair 0.5FTE to support the Chair with the increased workload next year.
5.3. Once CPRD has formalised the position recruitment will begin and suggestions for suitable candidates are welcomed – **ACTION CPRD**

6. **CPRD Audit**
   6.1. The CPRD Audit was agreed with minor changes.

7. **ISAC Audit**
   7.1.

8. **Potential protocol discussion 09_025R**
   8.1. Members discussed the protocol and agreed by consensus that no further discussion was required.

9. **Proposed CPRD policy on studies from the insurance/actuarial sector (CPRD Response to ISAC feedback on Protocol 13_102)**
   9.1. The members agreed that advice be communicated to CPRD regarding the unresolved issues; including the transparency issue around health research

10. **Generic Protocol on CPRD and Clinical Trial Services**
    10.1. Members approved the protocol with a recommendation to audit in future

11. **Proposed revision to the ISAC Guidance on the Content of Protocols for research using CPRD data**
    11.1. The members discussed the guidance and made various suggestions.
    11.2. A revised version is to be circulated for further comment in the near future – **ACTION CPRD**

12. **Proposal to change the ‘ISAC exemptions’ to include estimates of disease incidence and/or prevalence for regulatory requests**
    12.1. The committee agreed this would be approvable provided researchers followed a Standard Operating Procedure or CPRD protocol for calculating incidence and prevalence counts.

13. **The need to upload protocols under member review on the portal**
    13.1. Members agreed this is no longer required

**Information Items**

13.2. Review of outcomes for protocols received since the last meeting
    Noted.

14. **Reappointment of three ISAC members**
    14.1. The Chair was pleased to announce that Umesh Kadam, Simon Mitchell and Ruben Thanacoody have all been reappointed for a second term.

15. **CAG risk rating process**
    15.1. Noted.

16. **Feedback from applicant on protocol 11_061R**
17. MHRA Data mining workshop
   17.1. Noted.

18. AOB
   18.1. None.

Date and time of next meeting: Wednesday the 22\textsuperscript{nd} of January at 11.00 a.m.